

PATENT

UNITED STATES PATENT AND TRADEMARK OFFICE

In re: Jan Weber Confirmation No.: 5021
Serial No.: 10/763,825 Examiner: Thomas M. McEvoy
Filing Date: January 23, 2004 Group Art Unit: 3731
Docket No.: 1001.2246101 Customer No.: 28075
For: ELECTRICALLY ACTUATED MEDICAL DEVICES

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF REQUEST FOR REVIEW

CERTIFICATE FOR ELECTRONIC TRANSMISSION:

The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 9th day of March 2010.

By


Kathleen L. Boekley

Dear Sir:

Applicants request review of the final rejection in the above-identified application. No amendments are being filed with this Request.

This Request is being filed with a Notice of Appeal.

The review is requested for the reasons stated on the attached sheets of arguments.

This Request is signed by an attorney of record.

Respectfully submitted,

Jan Weber

By his Attorney,

Date:

3-9-2010


J. Scot Wickhem, Reg. No. 41,376
CROMPTON, SEAGER & TUFTE, LLC
1221 Nicollet Avenue, Suite 800
Minneapolis, MN 55403-2420
Telephone: (612) 677-9050
Facsimile: (612) 359-9349

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|---------------------------|---------------------------------------|-------------------|------------------|
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PRE-APPEAL CONFERENCE BRIEF

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By Kathleen L. Boekley
Kathleen L. Boekley

Dear Sirs,

Applicant submits that the Examiner's rejections contain at least the following clear errors and/or omissions of one or more essential elements needed for a *prima facie* rejection.

Claims 1-4, 9-13, 15-16, 24, 28, 30-32, 34-38, 50, 52, 54, 56-57, 61, 63, 71-74, and 80-86 stand finally rejected under 35 U.S.C. 103(a) as being unpatentable over Maseda (U.S. Patent No. 6,514,237) in view of Couvillon (U.S. Publication No. 2003/0236531). Applicant respectfully traverses this rejection. With regards to claim 1, nothing in Maseda or Couvillon, either taken alone or in combination, appear to disclose many elements of claim 1, including for example, "an active region comprising a conductive polymer disposed over the elongate body such that the medical device is expanded in at least one radial dimension relative to said axis upon volumetric expansion of the conductive polymer within the active region; wherein said active region surrounds said elongate body in the form of a continuous circumferential band".

The Final Office Action appears to assert that Maseda discloses "the circumferential band of composite strands expands and functions like a balloon", while citing column 6, lines 47-59. However, nothing in this passage appears to disclose "wherein said active region surrounds said elongate body in the form of a continuous circumferential band". Instead, as shown in Figure 5A, composite strips 500 appear to be oriented longitudinally along the length of the tubular body 114. As such, nothing in this passage or any other passage of Maseda appears to disclose "wherein said active region surrounds said elongate body in the form of a continuous

circumferential band".

The Final Office Action appears to acknowledge that Maseda fails to disclose "wherein said active region surrounds said elongate body in the form of a a continuous circumferential band", but turns to Couvillon for support. Applicant respectfully disagrees. As can be seen in Figures 2A-B, which are relied on by the Office Action, Couvillon appears to disclose a capture device including aperture 103 and one or more electroactive polymer actuators 110 that open and close the aperture 103 based on control signals sent from a control unit. The one or more electroactive polymer actuators 110 appear to be wrapped around the tubular structural element 102 so that they extend from one side of the aperture 103, around the tubular structural element 102, to the opposite side of the aperture 103. Clearly the electroactive polymer actuators 110 of Couvillon do not surrounds said elongate body in the form of a continuous circumferential band. In fact, the Final Office Action appears to acknowledge the Couvillon does not disclose a continuous circumferential band. Specifically, the Final Office Action states "Couvillon discloses that the electroactive polymer strips can expand a balloon-like structure (Figure 2B) in a continuous band (except for being interrupted by aperture 103; Figure 2A-B)". As the bands are interrupted by an aperture, the bands are clearly not circumferentially continuous.

Even though Couvillon does not appear to disclose an active region surrounding the elongate body in the form of a continuous circumferential band, the Final Office Action continues to assert that it would be obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture). Applicant respectfully disagrees.

As understood from the Supreme Court's decision under KSR, there must be some reason to make the claimed combination. MPEP § 2141 states:

The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. The Supreme Court in *KSR* noted that the analysis supporting a rejection under 35 U.S.C. 103 should be made explicit. The Court quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006), stated that "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396.

(Emphasis added). As can be seen, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. Applicant submits that the reasons

given in the Final Office Action do not provide sufficient articulated reasoning with some rational underpinning, as required by *KSR*. The reasons provided by the Final Office Action appear to be “it would be obvious to one of ordinary skill in the art, in view of the teachings of Couvillon and the suggestions of Maseda, to expand the balloon of Maseda using strips in the circumferential configuration of Couvillon (though not interrupted by an aperture)”. However, nothing in this statement appears to provide the required articulated reasoning with rational underpinning to support the legal conclusion of obviousness, as required by *KSR*. Specifically, nothing in this statement appears to provide any reason to modify the electroactive polymer actuators 110 of Couvillon to be continuous. However, the Final Office Action states “one of ordinary skill in the art would recognize that there is no need to make the strips discontinuous since there is no aperture. One of ordinary skill in the art would recognize that making the strips circumferentially discontinuous would result in uneven expansion of the balloon.” Applicant respectfully disagrees. Nothing in Couvillon or Maseda appear to disclose this. Instead, the only apparent reason for attempting to modify the device of Maseda with the teachings of Couvillon as suggested in the Final Office Action appears to come from Applicant’s own disclose, which is clearly improper.

Further, Applicant submits that modifying the capture device of Couvillon to make the electroactive polymer actuators 110 continuous would modify the capture device of Couvillon unsatisfactory for its intended purpose. MPEP § 2143.01 states: “[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984)”. Further, “[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959)”. Applicant submits that continuous electroactive polymer actuators in the capture device of Couvillon would modify the capture device to be unsatisfactory for its intended purpose or would change the principle operation of the device. As such, the suggested modification of the electroactive polymer actuators 110 of Couvillon is clear error.

In addition, as noted on page 3, the Final Office Action states “Maseda discloses: the electroactive polymer strands may be incorporated into various segments (or any segment) of the

device so that the device expands like and mimics a balloon in a balloon catheter (col. 3, lines 3-6)". From this, it appears that suggested reason for combining Couvillon with Maseda (to solve the problem of expanding the device like a balloon) is already solved by Maseda. As such, a person of ordinary skill in the art at the time of the invention would not have looked to Couvillon to expand the device of Maseda like a balloon. Notably, the only reason for combining the teachings of Couvillon and Maseda in the manner suggested by the Final Office Action appears to come from Applicant's own specification, which is clearly improper. For at least these reasons, claim 1 is believed to be patentable over Maseda and Couvillon. For similar reasons and others, claims 2-4, 9-13, 15-16, 24, 71-74, and 80-84 are believed to be patentable over Maseda and Couvillon.

With regards to claim 28, nowhere does Couvillon or Maseda appear to disclose many of the elements of claim 28, including for example, "an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region".

Maseda appears to disclose incorporating an EAP material (e.g., composite strands 500) in a balloon catheter to induce movements such as wiggling, slithering, twirling, bending, pulsing, vibrating, rotation, expansion, contraction or elongation. While Maseda does appear to disclose that balloon 118 or other portions of the balloon catheter may include the EAP composite strands, nothing in Maseda appears to disclose providing the composite strands over an elongate body and beneath the balloon to selectively expand the balloon. Further, nowhere does Maseda appear to disclose the composite strands being disposed over an elongate body and beneath any portion of the catheter. As such, nothing in Maseda appears to disclose "an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region", as recited in claim 28.

As noted above, Figures 2A-B of Couvillon (relied on by the Office Action) appear to disclose a capture device including aperture 103 and one or more electroactive polymer actuators 110 that open and close the aperture 103 based on control signals sent from a control unit. The one or more electroactive polymer actuators 110 appear to be wrapped around the tubular

structural element 102 so that they extend from one side of the aperture 103, around the tubular structural element 102, to the opposite side of the aperture 103. Figure 6 of Couvillon (relied on in the Final Office Action) appear to disclose the strands beneath the balloon. However, nothing in Couvillon appears to disclose "an active region comprising a conductive polymer disposed over the elongate body and beneath the balloon, said active region being adapted to radially advance at least a portion of the balloon when the balloon is in a substantially uninflated state by the volumetric expansion of the conductive polymer within the active region", as recited in claim 28. Further, nothing in the Final Office Action appears to provide any articulated reasoning with some rational underpinning to provide a conductive polymer disposed both over the elongate body and beneath the balloon. For at least these reasons, claim 28 is believed to be patentable over Maseda and Couvillon. For similar reasons and others, claims 28, 30-32, 34-38, and 85-86 are believed to be patentable over Maseda and Couvillon.

For similar reasons and others, claim 50 is believed to be patentable over Maseda and Couvillon. For similar reasons and others, claims 52, 54, 56-57, 61, and 63 are also believed to be patentable over Maseda and Couvillon.

For additional remarks/arguments regarding other claims and/or rejections, Applicants respectfully refer the Panel to pages 11-17 of the Amendment After Final filed January 22, 2010, which is herein incorporated by reference.

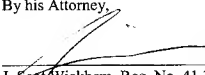
For at least the reasons mentioned above, all of the pending claims are allowable over the cited prior art. It is respectfully submitted that all pending claims are now in condition for allowance. Issuance of a Notice of Allowance in due course is requested. If a telephone conference might be of assistance, please contact the undersigned attorney at (612) 677-9050.

Respectfully submitted,

Jan Weber

By his Attorney,

Date: 3-9-2010


J. Scott Wickhem, Reg. No. 41,376
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